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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/777,471	02/12/2004	Adnan M.M. Mjalli	41305-296607	2244

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EXAMINER	
STOCKTON, LAURA LYNNE	

ART UNIT	PAPER NUMBER
1626	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/777,471	MJALLI ET AL.	
	Examiner	Art Unit	
	Laura L. Stockton, Ph.D.	1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 May 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,6-32,36,37,39 and 63-81* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3, 6-32, 36, 37, 39 and 63-81* is/are rejected.

7)☒ Claim(s) *4* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

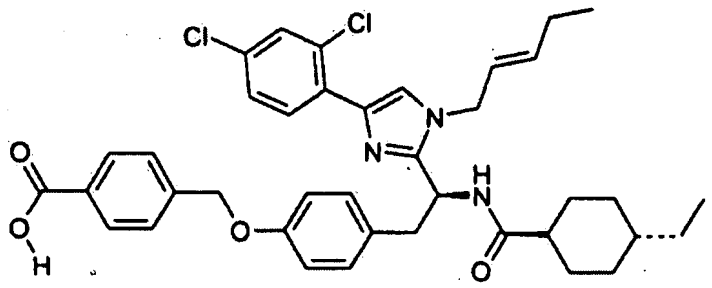
DETAILED ACTION

Claims 1-4, 6-32, 36, 37, 39 and 63-81 are pending in the application.

Election/Restrictions

Applicant's election with traverse of Group III (claims 1-45), and the species of Example 146 found on pages 185-186 of the instant specification (reproduced below), in the reply filed on October 27, 2006 was acknowledged in the previous Office Action.

Example 146



4-(4-{2-[4-(2,4-Dichloro-phenyl)-(E)-1-pent-2-enyl-1H-imidazol-2-yl]- (2S)-2-[(trans-4-ethyl-cyclohexanecarbonyl)-amino]-ethyl}-phenoxymethyl)-benzoic acid

The claims within elected Group III and the IDS were examined to the extent that they are readable on the elected species of Example 146. Since no prior art was found on the elected species, the examination was expanded within elected Group III until art was found, in which case, the examination stopped and art was applied against the claims. Note, M.P.E.P. § 803.02. The subject matter of the expanded search (inclusive of the elected species of Example 146) is as follows:

W is $N(R_4)$;

X is -C(O)-;

$\mathbf{Ar_1}$ is an optionally substituted phenyl;

$\mathbf{Ar_2}$ is an optionally substituted phenylene; and

all other variables are as defined.

The claims that are embraced by the subject matter of the expanded search are claims 1-45. The requirement was deemed proper and therefore made FINAL in the previous Office Action.

Subject matter not embraced by the above indicated expanded search is withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention(s), there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on October 27, 2006.

Rejections made in the previous Office Action that do not appear below have been overcome. Therefore, arguments pertaining to these rejections will not be addressed.

Claim Objections

Claims 63-81 are objected to for being substantial duplicates of the claims from which they depend. Since no other ingredient besides the compound is recited in newly added pharmaceutical composition claims of 63-81,

the claims are considered duplicates of the claims from the compound claim from which claims 63-81 depend. When two claims in an application are duplicates, or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to reject the other as being a substantial duplicate of the allowed claim. M.P.E.P. §706.03(k).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 30 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for alkylating agents, antimetabolites, plant

alkaloids, antibiotics, hormones, analgesics, NSAIDSs, DMARDs, sulfonylureas, biguanides, acarbose, PPAR agonists, insulin, GLP-1, cholinesterase inhibitors, antipsychotics, antidepressants, anticonvulsants, HMG CoA reductase inhibitors and cholestyramine, does not reasonably provide enablement for biologic response modifiers, glucocorticoids, DPP-IV inhibitors, GK activators, insulin mimetics, insulin secretagogues, insulin sensitizers, GLP-1 mimetics and fibrates. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

In *In re Wands*, 8 USPQ2d 1400 (1988), factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. § 112, first paragraph, have been described. They are:

1. the nature of the invention,

2. the state of the prior art,

3. the predictability or lack thereof in the art,

4. the amount of direction or guidance present,

5. the presence or absence of working examples,

6. the breadth of the claims,

7. the quantity of experimentation needed, and

8. the level of the skill in the art.

The nature of the invention

Applicant is claiming compositions in claim 30 further comprising lists of additional therapeutic agents but some of these agents are not adequately described in the instant specification as noted above.

The state of the prior art and the predictability or lack thereof in the art

The state of the prior art is that the pharmaceutical art remains highly unpredictable. The various broad listing of additional therapeutic agents without giving any indication of compounds embraced by the language biologic response modifiers,

glucocorticoids, DPP-IV inhibitors, GK activators, insulin mimetics, insulin secretagogues, insulin sensitizers, GLP-1 mimetics and fibrates would lead one skilled in the art to guess Applicant's intent. The existence of this obstacle establishes that the contemporary knowledge in the art would prevent one of ordinary skill in the art from accepting any therapeutic regimen on its face.

The amount of direction or guidance present and the presence or absence of working examples

Applicant has not provided an examples or adequately described compounds that are embraced by the language biologic response modifiers, glucocorticoids, DPP-IV inhibitors, GK activators, insulin mimetics, insulin secretagogues, insulin sensitizers, GLP-1 mimetics and fibrates.

The quantity of experimentation needed

The nature of the pharmaceutical arts is that it involves screening *in vitro* and *in vivo* to determine

which products exhibit the desired pharmacological activities for each of the diseases and disorders disclosed. The quantity of experimentation needed would be undue when faced with the lack of direction and guidance present in the instant specification in regards to the various additional therapeutic agents being claimed in the pharmaceutical composition, and when faced with the unpredictability of the pharmaceutical art. Thus, factors such as "sufficient working examples", "the level of skill in the art" and predictability, etc. have been demonstrated to be sufficiently lacking in the instant case for the instant method claims.

The level of the skill in the art

Even though the level of skill in the pharmaceutical art is very high, based on the unpredictable nature of the invention and state of the prior art and lack of guidance and direction, one

skilled in the art could not use the claimed invention without undue experimentation.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-3, 5-32, 36, 37, 39 and 63-81 are rejected under 35 U.S.C. 103(a) as being unpatentable over Thurieau et al. {WO 2002/10140} and Thurieau et al. {WO 99/64401}, each taken alone or in combination with each other when similar utilities are asserted.

Determination of the scope and content of the prior art (MPEP §2141.01)

Applicant claims imidazole compounds. **Thurieau et al. '140** (pages 2-6, 20, 21, 23-25, 39-41 and 56-58; and especially Examples 33 & 34 on page 155; Example 47 on page 134) and **Thurieau et al. '401** (pages 2-7, 20, 21 and 24-26, 39-41 and 56-58; and especially Example 33 on page 133) each teach imidazole compounds that are structurally similar to the instant claimed compounds.

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The difference between the compounds of the prior art and the compounds instantly claimed is that the instant claimed compounds are generically described in the prior art.

Finding of prima facie obviousness--rational and motivation (MPEP §2142-2413)

The indiscriminate selection of "some" among "many" is *prima facie* obvious, *In re Lemin*, 141 USPQ 814 (1964). The motivation to make the claimed compounds derives from the expectation that structurally similar

compounds would possess similar activity (e.g., an anti-inflammatory).

One skilled in the art would thus be motivated to prepare products embraced by the prior art to arrive at the instant claimed products with the expectation of obtaining additional beneficial products which would be useful in treating, for example, inflammation. The instant claimed invention would have been suggested to one skilled in the art and therefore, the instant claimed invention would have been obvious to one skilled in the art.

Response to Arguments

Applicant's arguments filed May 14, 2007 have been fully considered but they are not persuasive. Applicant argues that: (1) there is very little overlap between the genera disclosed in the cited prior art and the instant claimed invention; and (2) based on the decision in *In re Baird*, 16 F.3d 380, 29 USPQ2d 1550

(Fed. Cir. 1994), one cannot select specific moieties from a genus to render a smaller genus obvious.

All of Applicant's arguments have been considered but have not been found persuasive. Thurieau et al. '140 and Thurieau et al. '401 each teach imidazole compounds that are structurally similar to the instant claimed compounds. There is an overlap between the subject matter taught in the prior art and the invention instantly claimed. The size of the overlap is of no consequence when determining an obviousness-type rejection under 35 USC 103. Further, it is strongly disagreed that the instant claimed genus is smaller than the genera found in the cited prior art, when it is just the opposite. The instant claimed genus {instant claim 1 covering about 13 pages} is considered vast in comparison to the genera taught in the prior art. Applicant states that the definition of Ar_1 has been currently amended so that none of the enumerated compounds from the cited prior art. It is

agreed that none of the enumerated compounds from the cited prior art are embraced by the currently amended claims. However, each of the cited prior art references direct one skilled in the art toward other generically embraced compounds that fall within the scope of the currently amended claim 1 {i.e., the instant Ar_1 variable, which is currently amended, can be substituted with a substituent such as a bromo}. See pages 39-41 and 56-58 in Thurieau et al. '140 and in Thurieau et al. '401. The rejection is deemed proper and therefore, maintained.

Allowable Subject Matter

The elected species of Example 146, found on pages 185-186 of the instant specification, is allowable over the art of record.

Claim 4 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened

statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

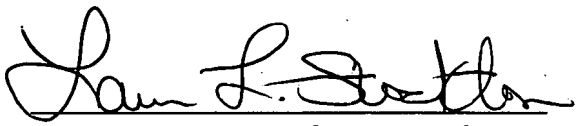
This application contains subject matter drawn to an invention(s) nonelected (see above identified expanded search) with traverse in the reply filed on October 27, 2006. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura L. Stockton whose telephone number is

(571) 272-0710. The examiner can normally be reached on Monday-Friday from 6:15 am to 2:45 pm. If the examiner is out of the Office, the examiner's supervisor, Joseph McKane, can be reached on (571) 272-0699.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

The Official fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.



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July 12, 2007